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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/807,590               | 03/24/2004  | Mark Girard          | 10123/04201         | 3798             |
| 30636                    | 7590        | 11/01/2007           | EXAMINER            |                  |
| FAY KAPLUN & MARCIN, LLP |             |                      | DESGANTO, MATTHEW F |                  |
| 150 BROADWAY, SUITE 702  |             |                      | ART UNIT            | PAPER NUMBER     |
| NEW YORK, NY 10038       |             |                      | 3763                |                  |
| MAIL DATE                |             | DELIVERY MODE        |                     |                  |
| 11/01/2007               |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                 |               |
|------------------------------|-----------------|---------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |
|                              | 10/807,590      | GIRARD ET AL. |
| Examiner                     | Art Unit        |               |
| Matthew F. DeSanto           | 3763            |               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 16 August 2007.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-10, 13-16 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10, 13-16 and 18-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Specification***

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:
2. The claim recites a first portion and a second portion, but this language cannot be found in the specification.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10, 13-16, 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cupp et al. (USPN 4,892,518), and further in view of Ensminger et al. (USPN 5,542,923).

Cupp et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first well of

the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figures 2, 7, 11A and entire reference), but fails to teach the first arm separated from the housing by a gap.

Ensminger et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first well of the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figure 4 and entire reference) and teaches a gap (the space between the first and second arm [92, 92']).

Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Cupp et al. with the teachings of Ensminger et al., since the limitations not taught in Cupp et al. is an obvious matter of design choice to one skilled in the art. Applicant fails to disclose any criticality and/or unexpected results and even teaches that one of ordinary skill would understand how to modify the device depending on the medical situation (applicant's specification paragraph 0012). Further more, it appears that the invention would perform equally well with any spacing between the first and second arm, whether it be an opening or just a space between the first and second arm, as taught by Cupp et al. (in reference number 161) or the gap between the housing as taught and shown in figure 4 of Ensminger for the reasoning that the space still serves the same function, which is to maintain separate lumens to prevent the medicaments from mixing. Hence forming a space between the housing and the arms are a mere obvious modification that would require routine skill in the art:

5. Claims 1-10, 13-16, 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger et al. (USPN 5,542,923).

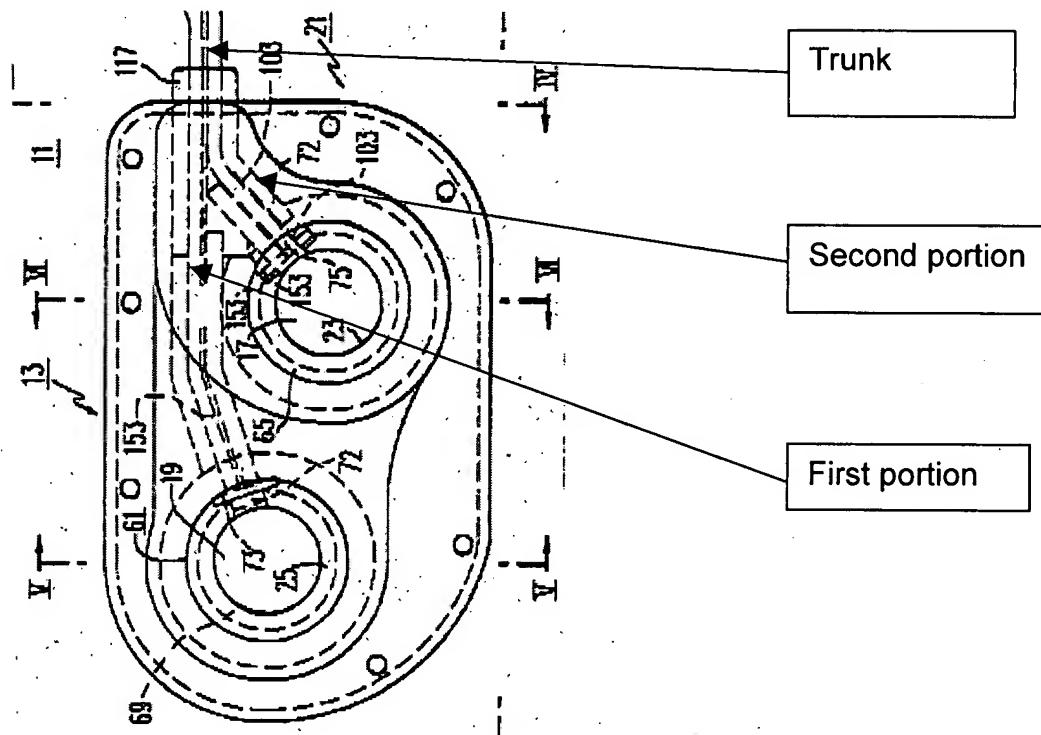
Ensminger et al. discloses an F-shaped connector for a dual well port, comprising: a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens; a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen

being fluidly connectable to a first well of the dual well port; and a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the first well before reaching the distal ends of the first and second connector lumens (see figure 4 and entire reference) and teaches a gap (the space between the first and second arm [92, 92']), but fails to teach the specific angels of the first and second arms.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify the device of Ensminger et al., since the limitations not taught in Ensminger et al. is an obvious matter of design choice to one skilled in the art. Applicant fails to disclose any criticality and/or unexpected results and even teaches that one of ordinary skill would understand how to modify the device depending on the medical situation (applicant's specification paragraph 0016). Further more, it appears that the invention would perform equally well with any angle between the first and second arm and the tubing connected to the first and second arm, the reasoning that the angle of the arms and tubing doesn't change the overall concept of the invention, which is to provide a compact delivery device that allow separate medicament to be injected into the body, wherein the separate medicament is prevented from mixing together. Therefore, the modifications to the first and second arms would be an obvious one and would only take routine skill in the art to fulfill the requirements of the claims.

***Response to Arguments***

6. Applicant's arguments with respect to the claims have been considered but are not persuasive.
7. With regards to both rejections the applicant fails to show criticality for the opening as well as the specific shape of the arms and lumens, thus the examiner maintains his rejections, since one skilled in the art would find the modification an obvious design choice.
8. Cupp et al. teaches the "f shaped flow connector" with the first portion on the first arm and the second portion in the second arm. See the image below and figure 4 in Ensminger shows a gap between the first and second portion and the housing.



***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

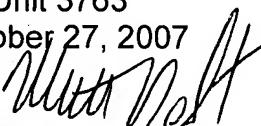
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto  
Art Unit 3763  
October 27, 2007

  
MATTHEW P. DESANTO  
PRIMARY EXAMINER